

Claims 1, 2, 4-6, 8, 9, 11, 14, 15, 18, 19, 21-25, 27, 30, 31 and 33 stand rejected as obvious over Bell. The Bell reference is stated to disclose a center-filled chewing gum composition including a shell portion and a center-fill. The center-fill can include a mixture nutraceuticals and may include a hydrocolloid which may function as a suspending agent. The rejection is hereby traversed and reconsideration is respectfully requested.

In the latest Office Action, the Patent Examiner commented on the previously submitted Declaration and the principal inventor, Jesse John Kiefer. Two comments were made about the Declaration. The first is that the Bell reference discloses a center-fill which does not have gum base as in the present claims. The second comment is that although Bell does not disclose the calcium compound particle size that is present in the claims of the record, the Declaration does not provide factual evidence to support the conclusion that particle size of the calcium compound is critical.

The present invention is directed to a center-fill chewing gum in which gum base is absent from the core. The core contains a non-water soluble or sparingly water soluble calcium-containing compound. The center-fill chewing gum is therefore being used as a delivery vehicle to provide a minimum daily nutritional amount of calcium to a user by chewing a reasonable number (3 to 5) of pieces of the chewing gum composition per day. The present application has made it clear that the delivery of calcium via a chewing gum delivery vehicle is problematic and

anything but routine. First, the minimum daily nutritional amount of calcium required from the delivery vehicle by chewing a reasonable number of pieces per day is relatively high. Thus, using chewing gum as a vehicle for delivering calcium has as a first major issue, a high level of calcium that must be present in each chewing gum piece in order to be able to deliver the minimum daily nutritional amount of calcium as required in the present claims. The mere addition of high levels of calcium to a chewing gum composition can adversely affect the taste and sensory characteristics of the product, rendering it virtually useless as a delivery vehicle. Thus, one must find the right type of calcium and must find the right way of delivering the calcium from the chewing gum product.

Another obstacle of using chewing gum as a delivery vehicle for delivery of calcium is that calcium-containing compounds have a high affinity for chewing gum base. This means that the chewing gum base "traps" the calcium-containing compound and retains it thereby preventing it from being released into the oral cavity. One way of addressing this problem is simply to add more calcium to the chewing gum composition but, as previously indicated, Applicants have noted that this approach adversely affects the taste and sensory characteristics of the chewing gum composition.

Another approach is to encapsulate the calcium compounds with a material that resists entrapment by the gum base. At least one of the problems associated with this approach is the added cost of producing the chewing gum.

A further factor and a clearly limiting factor is the size of the individual serving of the chewing gum composition. Some calcium compounds contain a relatively small amount of calcium on a molecular weight basis. Such compounds are not desirable because too much of these compounds are needed to supply a sufficient amount of calcium through the chewing gum delivery vehicle.

Applicants have determined that the foregoing problems can be overcome by employing water insoluble or sparingly soluble calcium compounds which do not have a high affinity for the gum base and tend to have a relatively high calcium content on a molecular weight basis. Applicants further determined that employment of a center-fill chewing gum in which a portion of the gum is free of gum base would more effectively enable the release of the calcium-containing compound from the chewing gum composition.

Yet despite all of these considerations, Applicants determined that an effective chewing gum composition capable of delivering a desirable amount of calcium had not yet been realized. This is because the mere use of a center-fill chewing gum as a delivery vehicle wherein the calcium-containing compound is contained within the center-fill and away from the gum base, did not achieve a desirable product. Applicants discovered that it was necessary to ensure that the calcium-containing compounds are effectively suspended and dispersed throughout the center-fill portion. This provides a relatively high solids content and therefore

effective delivery of the calcium without adversely effecting the viscosity of the center-fill to a point where the taste and/or sensory characteristics of the chewing gum composition are compromised.

Thus, the calcium-containing compound must be effectively suspended and dispersed. As indicated in the Kiefer Declaration, water insoluble and sparingly soluble calcium compounds tend to settle in an aqueous center-fill. Settling is undesirable because there is an overloading of the calcium containing compound within a relatively small sector of the center-fill which causes consumers to perceive a gritty taste. While suspending agents such as hydrocolloids are useful for increasing the viscosity of a liquid medium, Applicants discovered that such materials within a center-fill could not retain the calcium-containing compound uniformly dispersed and stable in that condition during the life of the product. Further increasing the viscosity of the center-fill through additional amounts of suspending agents would likewise adversely affect the taste and sensory qualities of the product and could not therefore facilitate a chewing gum composition as a delivery vehicle for calcium.

As indicated in paragraph 13 of the Declaration, Applicants researched various particle sizes of the calcium-containing compound and found that if the average particle size was less than about 17 microns the proper balance between suspension and uniform dispersion of a calcium-containing compound and a desirable viscosity could be achieved while providing effective calcium release.

The Office Action states that the Keifer Declaration does not provide factual evidence to support the conclusion that particle size of the calcium-compound is critical. Applicants respectfully disagree. One of ordinary skill in the art, understanding of the present invention and all of the parameters and considerations that went into the present discovery, would understand that particle size was indeed critical.

More specifically, to prevent settling, Applicants had to apply Stoke's law and solve for the key variables of particle size (radius) and viscosity. Stoke's law is expressed as  $V = \frac{2}{9} \frac{r^2 g \Delta \rho}{\eta}$  where V is the velocity of the particle, r is its radius, g is gravity,  $\Delta \rho$  is the difference in density between the two phases and  $\eta$  is the viscosity of the continuous phase. Additionally, Stoke's law must be applied in the context of a range of factors that influence viscosity such as molecular structure, size as well as other factors. One of ordinary skill in the art would then appreciate that in the context of the present invention, particle size was a critical feature of the invention in order to achieve a uniform dispersion, with the absence of settling at a desirable viscosity.

As previously indicated, the Bell reference does not inherently disclose uniformly dispersed calcium in chewing gum by the mere mention of calcium in combination with a hydrocolloid because multiple factors not disclosed by Bell determine whether the calcium will be evenly dispersed and stably suspended.

Without solving for these factors, it cannot be assumed that the gum composition will provide a centerfill with uniformly dispersed calcium and therefore present organoleptic properties that are needed to provide a workable delivery vehicle.

Hydrocolloids function as effective stabilizers due to their hydrophilicity and their ability to form colloidal dispersions. The majority of food hydrocolloids are either natural materials such as exudates or chemically modified or chemically synthesized materials. These materials differ in their molecular structure, size and secondary molecular forces such as degree of hydrogen bonding, ionic interactions and the strength of van der Waals forces. Because of the large variety of hydrocolloids, one of ordinary skill in the art would have to engage in extensive experimentation to try to find the right hydrocolloid, if one were available.

Applicants chose an entirely different route by focusing, in part, on the particle size of the calcium containing compound and applying the principles of Stoke's law. Once appreciating that particle size would have a meaningful impact on the suspension of calcium within the center-fill of a chewing gum composition, Applicants were able to make use of the principles of Stoke's law to compute a desirable particle size range which appears in the claims. Accordingly, Applicants have established the criticality of particle size and have done so in connection with a center-fill chewing gum composition which is not obvious from the prior art of record.

It is therefore submitted that Bell does not teach or suggest the presently claimed invention and withdrawal of the rejections based on Bell is respectfully requested.

Claims 3 and 20 stand rejected over the combination of Bell further in view of Friello et al. or Glass et al. The rejection is hereby traversed and reconsideration is respectfully requested.

Claims 3 and 20 cover a Markush group of conventional suspending agents for inclusion in the center-fill portion of the chewing gum. As previously discussed in connection with Bell, the mere use of hydrocolloids within a center-fill does not ensure that the calcium-containing compound will be properly suspended therein. Applicants have pointed out that Bell is silent with respect to the considerations that support patentability of claim 1 and the addition of a suitable hydrocolloid does not alone achieve the objects of the present invention nor render obvious claims 3 and 20.

Claims 10, 12, 26 and 28 stand rejected as obvious over the combination of Bell further in view of Cherukuri et al. (U.S. Patent No. 4,352,823). The rejection is hereby traversed and reconsideration is respectfully requested.

The deficiencies of Bell have been previously discussed. Cherukuri does not disclose a center-fill chewing gum composition in which the center-fill is free of gum

base. The reference discloses a soft core portion which includes a particular type of gum base which is different than the conventional gum base as employed for chewing gum compositions. The Cherukuri soft core portion therefore contains a gum base which tends to trap any non-water soluble or sparingly water soluble calcium-containing compounds. Thus, it is improper to combine Cherukuri with Bell because Cherukuri would require the inclusion of the gum base in the center-fill portion. Thus, the combination of these two references is improper and the rejection based on these references should be withdrawn.

In view of the foregoing, Applicants submit that the present application is in condition for allowance and early passage to issue is therefore deemed proper and is respectfully requested.

It is believed that no fee is due in connection with this matter. However, if any fee is due, it should be charged to Deposit Account No. 23-0510.

Respectfully submitted,

  
Allen R. Kipnes, Esquire  
Registration No. 28,433  
Attorney for Applicant

Address All Correspondence to:  
Allen R. Kipnes, Esquire  
WATOV & KIPNES, P.C.  
P.O. Box 247  
Princeton Junction, NJ 08550  
(609) 243-0330